

### **Remarks**

Claims 30-33 currently stand rejected. Claims 30-33 are pending. Claims 30 and 32 have been amended. No new matter has been added. The Applicant believes that the comments that follow will convince the Examiner that the rejections provided in the December 21, 2007 Office Action have been overcome and should be withdrawn.

#### **I. THE EXAMINER'S REJECTIONS**

The Examiner rejected claims 30-33 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Claim 30 recites "an empirical formula of said sample." According to the Examiner, an empirical formula usually refers to a single chemical compound or molecule. However, the sample is limited in line 4 to contain several metabolic products; such metabolic products encompass chemical compounds. In the opinion of the Examiner, it is unclear how a sample comprising multiple chemical compounds could have a single empirical formula. In addition, claim 30 recites "each species." According to the Examiner, it is unclear to what in the sample the species is referring. (Office Action of December 21, 2007, page 2). The Examiner rejected claims 31-33 for depending from claim 30.

The Examiner rejected claims 30-33 under 35 U.S.C. § 103(a) as being unpatentable over Dasseux *et al.* U.S. Patent Publication No. 2002/0019023 A1 ("Dasseux") in view of Ji *et al.* Publication (J. Chem. Soc., Perkins Trans. 2 (2001), pages 585-591) ("Ji") in view of Mighell *et al.* Publication (Journal of Research of the

National Institute of Standards and Technology (1996) Volume 101, number 3, pages 273-280) ("Mighell").

Regarding claims 30, 32 and 33, the Examiner stated that Dasseux discloses a method of analyzing a drug-dosed sample that includes ionizing a drug-dosed sample with metabolic products; introducing said ions to the analysis region of a mass spectrometer; continuously monitoring the ions and detecting changes to the sample; determining the molecular weight of each species present in a sample to determine the empirical formula. Further, according to the Examiner, Dasseux discloses using electrospray ionization as well as chemical ionization (both of which are forms of Atmospheric Pressure Ionization as in claim 33). (Office Action of December 21, 2007, pages 3-4).

The Examiner agrees that Dasseux does not explicitly teach determining the empirical formula from the molecular weight or identifying each species by comparing the empirical formula to a database of formulas for known molecules. However, according to the Examiner, Ji teaches using FTMS to determine the molecular weight of a species and using molecular weight to determine the empirical formula. (Office Action of December 21, 2007, page 4).

Also, regarding claims 30 and 31, according to the Examiner, Mighell discloses a database that is searchable by querying the empirical formula and is updated with new scientific information. In the opinion of the Examiner, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to combine the teachings of Dasseux, Ji and Mighell for the benefit of obtaining additional data related to the identified chemical species. As stated by the Examiner, the databases of Mighell are

comprehensive and cross-referenced with other databases which provide additional data to be used as a basis for scientific research as an aid to scientific research. Further, as stated by the Examiner, one of the ways to search Mighell's database is to use the empirical formula; thus, after obtaining data from the method of Dasseux, one of ordinary skill in the art seeking to search Mighell's database would have been motivated to determine the empirical formula from the data of Dasseux. Finally, as stated by the Examiner, Ji teaches a method of determining the empirical formula from FTMS data such as the data in Dasseux; thus, one of ordinary skill in the art would have been motivated to combine the methods of Dasseux, Ji and Mighell to find additional data for scientific research. (Office Action of December 21, 2007, pages 4-5).

## **II. THE EXAMINER'S REJECTIONS AND OBJECTIONS SHOULD BE RECONSIDERED AND WITHDRAWN**

The Examiner rejected claims 30-33 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Claim 30 has been amended to recite: "determining molecular weight of each metabolic product present in said sample to determine an empirical formula for each metabolic product of said sample." The molecular weight of each metabolic product is used to determine an empirical formula for each metabolic product. Further, the term "each species" has been replaced by "each metabolic product" to clarify for the Examiner. In light of this amendment, the Applicant respectfully requests the withdrawal of the Examiner's 35 U.S.C. § 112, second paragraph rejection of claim 30.

Claims 31-33 depend from independent claim 30. The independent claim from which claims 31-33 depend has been amended to clarify its inventive aspect. Therefore, the Applicant respectfully requests the Examiner's withdrawal of the 35 USC § 112, second paragraph rejection of claims 31-33.

The Examiner rejected claims 30-33 under 35 U.S.C. § 103(a) as being unpatentable over Dasseux *et al.* U.S. Patent Publication No. 2002/0019023 A1 ("Dasseux") in view of Ji *et al.* Publication (J. Chem. Soc., Perkins Trans. 2 (2001), pages 585-591) ("Ji") in view of Mighell *et al.* Publication (Journal of Research of the National Institute of Standards and Technology (1996) Volume 101, number 3, pages 273-280) ("Mighell"). The Applicant respectfully disagrees and requests reconsideration of the Examiner's 35 U.S.C. § 103(a) in light of the following comments.

As recited in claim 30, the present invention discloses a method for analyzing a drug-dosed sample using a Mass Spectrometer, said method comprising the steps of: "determining a molecular weight of each metabolic product present in said sample to determine an empirical formula for each metabolic product of said sample [and] dynamically calculating and then displaying the error associated with each determination of a molecular weight of each said metabolic product present in said sample." By utilizing the FTMS system, the present invention uses a high mass accuracy to determine the molecular weight of the metabolic compounds. The system shows the elemental formulae for the detected metabolic products observed in the spectrum. It then shows the error associated with the calculation so that the user is ensured that a high mass accuracy reading has been obtained. (See Specification as published, Paragraph [0035]). Taken singly or in combination, Dasseux, Ji and Mighell do not teach, suggest or render obvious

this important feature of the present invention. Thus, the present invention is patentable over the prior art references for at least the reasons discussed above. Therefore, the Applicant respectfully requests the Examiner's withdrawal of the 35 U.S.C. § 103(a) rejection of claim 30.

Claims 31-33 depend from independent claim 20. By virtue of their dependencies, claims 31-33 have all the limitations of the independent claim from which they depend. Thus, claims 31-33 are patentable over the prior art references for at least the same reasons discussed above for claim 30. Therefore, the Applicant respectfully requests the Examiner's withdrawal of the 35 U.S.C. § 103(a) rejection of claims 31-33.

### III. CONCLUSION

Applicant submits that the all pending claims represent a patentable contribution to the art and are in condition for allowance. Early and favorable action is accordingly solicited.

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Respectfully submitted,



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